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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,794	05/24/2007	Abdessatar Chtourou	REGIM 3.3-093	5868

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,794	CHTOUROU ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-18* is/are pending in the application.

4a) Of the above claim(s) *1-6,11-15 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received March 18, 2010.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claim 10 is canceled. Claims 1-6, 11-15, 18 are withdrawn. Claims 7-9, 16-17 are currently under examination.

Priority: The request for priority to FRANCE 0312398, filed October 23, 2003, is acknowledged. A certified copy of the foreign priority document has been filed in this case on April 21, 2006 and is in a non-English language.

Objections and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9, 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 currently recites the phrase "correlating the residual content of high multimerization vWF with viral safety." However, said phrase is indefinite because it is unclear what "correlating" means, i.e. how is the residual content of high multimerization vWF correlated with viral safety; does a high content level indicate viral safety or does a low level content indicate viral safety. Further clarification is requested.

Claims 8-9, 16-17 are included in this rejection because they are dependent on claim 7 and fail to cure its defect.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9, 16-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chtourou et al. (US 6967239; previously cited).

For examination purposes, the instant claims have been interpreted as a method for preparing a virally safe FVIII solution comprising filtering a solution containing FVIII through nanometric filters having a pore size of 13 nm to about 25 nm, assaying the filtrate to determine the residual content of high-multimerization vWF, and correlating the residual content of high multimerization vWF with viral safety.

Chtourou et al. teach a method for preparing a FVIII solution comprising filtering a FVIIII solution through a virus filter that has a mean pore size of 13 to 17 nm and wherein the filtered FVIII solution is free of viruses and devoid of high molecular forms of vWF and FVIII-vWF complexes (col. 10 lines 5-19; claims 7-9, 16-17). Chtourou et al. teach a chromatographic step after virus inactivation in order to determine the vWF content and vWF multimer profile (col. 1 example 1, col. 9 example 7).

Regarding the limitations of claims 9, 16-17 (i.e. the titre reduction factor), it is believed that said limitations are within the scope of Chtourou et al. since Chtourou et al. teach the instant active step of filtering a FVIII solution through filters having the instant pore size, as well as teach the instant limitation that the vWF multimer content is less than 15%.

While Chtourou et al. do not explicitly teach correlating the residual content of high multimerization vWF with viral safety, it would have been obvious to one of ordinary skill in the art at the time the invention was made to correlate the relationship between viral safety and vWF content, i.e. it would be reasonable for one of ordinary skill to recognize that reducing the high molecular weight vWF multimers correlates with the viral retention capacity of said virus filter, since Chtourou et al. disclose that said virus filter has a viral retention (log) of >6.8 and results in a vWF multimer profile where vWF multimers $\geq$ 15 and $\geq$10 are present at levels of 0% and 3.3%, respectively (col. 9 Table 6 and Table 7, see also col. 10 lines 17-20). Therefore, one of ordinary skill would know that after filtration, a low level of vWF multimers would also indicate that the FVIII solution is free of viruses since said viruses have been retained on said virus filter.

In their remarks, Applicants assert that (1) claim 7 as amended recites and "correlating the residual content of high multimerization vWF with viral safety". Chtourou fails to satisfy this limitation. Chtourou fails to disclose any step of correlating residual content of high multimerization vWF and viral safety. Chtourou otherwise provides no indication that such a correlation exists. Chtourou thus could not anticipate claim 7. Further, Chtourou could not anticipate claims 8-9 and 16-17, because these depend from claim 7. Applicants note that case law supports the patentability of claims with such "correlating" steps. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* 581 F.3d 1336, 92 U.S.P.Q.2d1075 (Fed. Cir. 2009); *Metabolite Labs., Inc. v. Lab. Corp.,* 370 F.3d 1354, 71 U.S.P.Q.2d 1081 (Fed. Cir. 2004) (cert. dismissed, 548 U.S. 124, 126 S.Ct. 2921 (2006)). The *Metabolite* case is particularly notable, because the Federal Circuit affirmed validity of a claim reciting "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate" and the Office affirmed the *Metabolite* claims after reexamination (see Reexamination Control No. 90/008,305).

Applicant's arguments have been fully considered but they are not persuasive.

(1) Response: The rejection of the instant claims have been changed from a 35 U.S.C. 102(e) as being anticipated by Chtourou et al. to a 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chtourou et al.

As noted in the instant 102/103 rejection above, while Chtourou et al. do not explicitly teach correlating the residual content of high multimerization vWF with viral safety, it would have been obvious to one of ordinary skill in the art at the time the invention was made to correlate the relationship between viral safety and vWF content, i.e. it would be reasonable for

one of ordinary skill to recognize that reducing the high molecular weight vWF multimers correlates with the viral retention capacity of said virus filter, since Chtourou et al. disclose that said virus filter has a viral retention (log) of >6.8 and results in a vWF multimer profile where vWF multimers ≥ 15 and ≥10 are present at levels of 0% and 3.3%, respectively (col. 9 Table 6 and Table 7, see also col. 10 lines 17-20). Therefore, one of ordinary skill would know that after filtration, a low level of vWF multimers would also indicate that the FVIII solution is free of viruses since said viruses have been retained on said virus filter.

For at least these reasons, the Chtourou et al. is still believed to be relevant art.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/
Primary Examiner, Art Unit 1656

June 14, 2010

M. Tsay
Art Unit 1656